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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/069,389 | 07/01/2002 | Arthur Schaffer | 6727/OK318USO | 3278 |

7590 03/04/2005
S. Peter Ludwig
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805 Third Avenue
New York, NY 10022-7513

EXAMINER

ROBINSON, KEITH O NEAL

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1638 | |

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

H/L

| | | | |
|------------------------------|---|---|--|
| Office Action Summary | Application No. 10/069,389 | Applicant(s) SCHAFFER, ARTHUR | |
| | Examiner Keith O. Robinson, Ph.D. | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/21/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action. This Office Action is in response to Applicant's amendments, arguments and affidavit filed 7 December 2004, and the following **second non-final** office action is set forth. Applicant's amendments have overcome the outstanding rejection under 35 U.S.C. 112, second paragraph; and the art rejections over Tanksley et al and Azanza et al. However, Applicant's amendment introduced new matter, as stated below. Cancellation of the new matter will result in reinstatement of these art rejections.

Claims 1-16 are under examination.

Objections

Photograph D6 of the Declaration, filed 7 December 2004, is objected to for not being decipherable. Examiner cannot examine the photo, as it does not show the phenotype due to the photo being "blacked out".

Claim Rejections - 35 USC § 112, first paragraph

Claims 1, 11, and 16 and dependents are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain the phrase "... wherein the ripe fruit has lost at least 30% of its red ripe fruit water content.". There is no basis for these claims in the specification, and therefore the phrase is considered NEW MATTER. Table 2 on page 9 of the specification gives a single data point of 31% water loss, which does not provide literal support for the broad range of "at least 30%", which has no upper limit.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office Action filed 9 June 2004, pages 2-4, as applied to claims 1-16. Applicant's arguments, filed 7 December 2004 have been fully considered but they are not persuasive.

Applicant states that the teaching in the specification of crossing a single *Lycopersicon* species, namely *L. hirsutum*, with *L. esculentum* is enabling for other wild *Lycopersicon* species.

This is not persuasive. The Examiner has reviewed the evidence provided in the Declaration of Dr. Schaffer; however, this data does not provide evidence that other wild *Lycopersicon* species can be crossed with *L. esculentum* to obtain a tomato fruit characterized by the capability of natural dehydration while on a tomato plant. Applicant

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provides anecdotal statements that in addition to *L. hirsutum*, *L. pennellii* can be crossed with *L. esculentum* to produce tomato plants that have tomato fruit with the capability of natural dehydration while on a tomato plant (see page 12, first full paragraph to page 13, end of first paragraph and page 21 of Appendix A, another patent, application by Schaffer and Hovav). However, Figures 6-7 as discussed in Appendix A have not been submitted and therefore, have not been considered. In the absence of interpretable Figures, Applicant has not provided any data to support or elaborate his anecdotal statements.

Applicant also states that Appendix B (Frary et al, 2004) notes that the genetic trait of epidermal reticulation is observable in *L. esculentum* introgression lines derived from additional wild species, including *L. parviflorum* and *L. peruvianum*. However, this reference does not provide evidence of the claimed invention of natural dehydration of tomato fruits on tomato plants. The *er* phenotype of Frary et al is not the same as the *Cwp* gene of the instant invention. Tomato fruits with the *Cwp* phenotype show microcracks whose presence was verified by either magnifying glass or binocular microscope (see Appendix A, page 5, second and third paragraphs), whereas, the tomato fruits with the *er* phenotype show extreme cracks which are visually evidenced as undesirable epidermal reticulation (see page 3 of Appendix A, fourth and fifth paragraphs; see also p. 492 of Frary et al, column 2, last full sentence).

Applicant further states that there is a clear distinction and a fundamental difference between increase in soluble solids content and resulting reduction in water

content and dehydration of a ripe tomato fruit, so that the Examiner's reliance upon evidence regarding soluble solids is not pertinent.

The Examiner acknowledges Applicant's amendment of the claims to include recitation of fruit dehydration producing a reduction in red ripe fruit water content of at least 30%; however, there is not basis in the specification for this language.

Furthermore, the Examiner's evidence demonstrates the general unpredictability in modifying tomato fruit water content, whether by surface dehydration or internal water reduction.

Applicant states that the *L. esculentum* plant of claims 15 and 16 are readily obtainable by a repeatable method set forth in the specification and therefore, a deposit is not required.

This is not persuasive. Though the specification does disclose the steps involved in the derivation of said tomato plants, it is known in the art that the introgression of alleles from one background to another is unpredictable, as discussed in the previous Office Action. In fact, the specification states that only 25 of the 350 F2 plants (~7%) produced fruit from a cross of 1630 and LA 1777, and of those 25 F2 plants, only 3 (~0.8%) were selected for the desired trait. This does not constitute a readily obtainable, repeatable method, thus it is necessary for Applicant to meet the deposit requirement.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office Action filed 9 June 2004, pages 6-8, as applied to claims 1-16. Applicant's arguments, filed 7 December 2004 have been fully considered but they are not persuasive.

Applicant states that the specification refers explicitly to Accession Number LA 1777, which is deposited and classified as a "representative" *L. hirsutum*, as evidenced by the classification in the Report of the Tomato Genetics Cooperative (Appendix C of the Declaration).

This reference, though listing LA 1777, merely provides list of wild tomato relatives and does not provide a description of this accession in terms of its genetic, morphological, and/or physiological composition. Furthermore, no conserved genetic sequences or morphological characteristics among the entire list of accessions are demonstrated.

Claim Rejections - 35 USC § 102

Claims 15-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Eshed and Zamir (Theor. Appl. Genet. 88: 891-897, 1994), as stated on pages 9-10 of the last Office Action. The rejection is maintained.

Applicant states in the Schaeffer Declaration of December 7, 2004 that the above reference showed micro-fissures and dehydration phenotype that is claimed in claims

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15-16 in the fruit of IL4.4 and that this allele is the *Cwp* allele as claimed in Appendix A (see page 2, paragraph number 6 of the Declaration). As the claims are broadly drawn to any tomato plant which produces fruit with natural dehydration, the above reference is appropriate for rejection of the claims under 35 U.S.C. 102(b). The claimed loss of at least 30% ripe fruit water content would be an inherent property, since the plants contain the same gene as the gene responsible for this trait.

Claim Rejections - 35 USC § 102 (New Rejections)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaffer (US Patent 5,817,913, October 6, 1998). The claims are broadly drawn to any tomato fruit of the *Lycopersicon esculentum* species characterized by a “capability” of natural dehydration while on a tomato plant. The instant specification teaches that said tomato plants are derived from the cross of *L. esculentum* breeding line 1630 and the wild species *L. hirsutum* (LA 1777) and that three F2 plants were selected from an F2 population of about 350 plants, wherein the instantly claimed wrinkled fruits were produced by one F3 plant, namely F3-203-10 (see page 5, line 29 to page 6, line 11).

Schaffer teaches tomato plants derived from the cross of *L. esculentum* breeding line 1630 and the wild species *L. hirsutum* (LA 1777) and the selection of F2 plants from

an F2 population of about 350 plants, wherein F3 plants including F3-203-10 were produced (see column 3, line 58 to column 4, line 19; column 4, Table 1, last line).

Thus, the F3-203-10 plants taught by Schaffer inherently have the “capability” of natural dehydration while on a tomato plant.

Claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Eshed et al (Genetics 141: 1147-1162, 1995) in light of the Schaeffer Declaration (see page 2, paragraph number 6). The claims are drawn to any tomato fruit characterized by a capability of natural dehydration while on a tomato plant.

The Declaration by Applicant teaches the introgression line 4.4 that is derived from the interspecific hybridization of *L. esculentum* and an additional wild species *L. pennellii* that contains the analogous introgression as the *L. hirsutum*-derived genotypes wherein tomato fruits of said line show micro-fissures and dehydration.

Eshed et al also teach the introgression line 4.4 derived from the interspecific hybridization of *L. esculentum* and the wild species *L. pennellii* (see page 1160, Figure 3). As the Declaration states that tomato fruits of said line show micro-fissures and dehydration, it would be inherent that the plants taught by Eshed et al would also show tomato fruits with micro-fissures and dehydration, and be inherently capable of at least 30% ripe fruit water loss. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property,

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then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant states that the prior art publication of "bush tomatoes" referred to in Appendix D (The Rural Industries) is not a tomato, is not of the *Lycopersicon* genus, and is not hybridizable with the *Lycopersicon esculentum*, as asserted on page 4 of the Schaeffer declaration, paragraph 15. The Examiner has reviewed said reference and finds Applicant's declaration to be persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 24, 2005

KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.